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No. 98-1284

IN THE

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner,

v.

GREGORIA GRIJALVA, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* HEALTH INSURANCE ASSOCIATION OF AMERICA AND BLUE CROSS AND BLUE SHIELD ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF AMICI CURIAE

The Health Insurance Association of America ("HIAA"), based in Washington, D.C.,[1] represents approximately 250 member companies that include health maintenance, preferred provider and other managed care organizations. Together, HIAA members provide medical expense and supplemental

[1] No party or its counsel has authored any part of this brief. No person or entity other than the Health Insurance Association of America and the Blue Cross and Blue Shield Association and their counsel has made a monetary contribution to the preparation or submission of this brief.

insurance, as well as long-term care insurance and disability income protection, to more than 110 million Americans. Managed care organizations owned and operated by HIAA member companies serve millions of Medicare beneficiaries throughout the United States.

The Blue Cross and Blue Shield Association ("BCBSA"), based in Chicago, Illinois, is a not-for-profit association representing the interests of fifty-two independent, locally operated Blue Cross and Blue Shield Plans, with a collective enrollment of more than seventy-one million subscribers. The majority of the member Plans operate Medicare managed care health programs serving more than one million beneficiaries nationwide. Together, the Plans also serve over fifteen percent of the total Medicaid managed care population.

Both HIAA and BCBSA (collectively "the Associations") believe that the Medicare managed care program is an essential component of the federal government's effort to ensure Medicare's financial survival and to meet the health care needs of an aging population. Accordingly, they are committed to promoting laws and policies that encourage successful Medicare managed care contracting. In this context, they develop and advocate policies to improve the health care system's quality, affordability, accessibility, efficiency and responsiveness. All of these issues are directly affected by the decisions below.

The Associations' members also have a direct and significant stake in the outcome of this case. Their managed care organizations will bear the brunt of the injunction entered by the district court and affirmed by the Ninth Circuit. If the Secretary of Health and Human Services ("the Secretary") is forced to implement the detailed procedural requirements of the injunction, managed care organizations will be forced to shift limited financial resources away from funding the provision of supplemental benefits for beneficiaries and allocate them instead to paperwork and administrative functions. Ultimately, the injunction would make it more

difficult for managed care organizations to participate in the Medicare+Choice program recently enacted by Congress as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, in its continuing efforts to ensure the viability of the Medicare program.

Counsel for the parties have consented to the filing of this *amicus* brief. Their letters of consent have been filed with the Clerk.

REASONS FOR GRANTING THE WRIT

This case presents issues of great importance to the future of Medicare. As medical costs have increased and the population has aged,[2] Congress and the Secretary have increasingly relied on private sector health maintenance organizations and similar managed care entities (collectively, "HMOs") to provide Medicare beneficiaries high quality medical care in an efficient and cost-effective manner. The evolving legislative and regulatory framework, reflected most recently in the Medicare+Choice program, requires accommodation of numerous complex and often conflicting medical, economic and social issues. Policy choices are difficult, trade-offs are necessary and change is constant. Congress and the Secretary continue to struggle to strike the appropriate balance between regulatory protections and efficient, cost-effective delivery of health care services.

Yet at a time when innovation and flexibility are crucial, the Ninth Circuit has stepped in and placed the Secretary and the HMOs that she regulates in a constitutional straitjacket.

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[2] The Health Care Finance Administration ("HCFA") projects that national health expenditures will double from $1.1 trillion in 1996 to $2.1 trillion in 2007. *See The Next Ten Years of Health Spending: What Does the Future Hold?*, HEALTH AFF., Sept.-Oct. 1998. According to the Census Bureau, by 2025, the population age 65 and older will nearly double from about 34 million today (12.7% of the total population) to 62 million (18.5%). BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES 1998, at 25.

The court of appeals affirmed a nationwide injunction requiring the Secretary to impose numerous specific and stringent requirements governing the manner in which HMOs may deny – or even alter – medical treatment to Medicare beneficiaries who have chosen to enroll in managed care programs. This decision, as a practical matter, takes the ability to regulate treatment decisions by private Medicare HMO contractors away from the Congressionally designated agency with expertise in the management and delivery of health care services and turns it over to a single district court that did not even hear medical testimony to clarify the terms of its injunction. Pet. App. 68a.

The Ninth Circuit endorsed this judicial intrusion into HMO Medicare regulation by affirming two clearly erroneous legal determinations made by the district court. First, the court below concluded that because the federal government extensively regulates Medicare HMO contractors, the decisions of those private health care providers as to whether medical treatment for their patients is appropriate and necessary constitute "federal action," subjecting the HMOs to constitutional requirements of due process. Pet. App. 8a-12a. Second, the court concluded that the applicable federal regulations (which have since been superseded) did not give the nationwide class of Medicare beneficiaries who voluntarily enrolled in HMOs the "process" that was "due" under the circumstances. Pet. App. 12a-18a.

This Court should grant the Secretary's petition, summarily reverse the court below and remand with instructions to vacate the injunction in light of *American Manufacturers Mutual Insurance Co. v. Sullivan*, No. 97-2000 (U.S. Mar. 3, 1999). The Court's holding in *Sullivan* that medical payment decisions made by private workers' compensation insurers do not constitute "state action" applies with equal force to the medical treatment decisions made by private Medicare HMO contractors that were at issue in the case below. The Ninth Circuit here, like the Third Circuit in *Sullivan*, confused government regulation with government

action. In this respect, the Ninth Circuit's decision is fundamentally inconsistent not only with *Sullivan* but with this Court's prior holding in *Blum v. Yaretsky*, 457 U.S. 991 (1982).

The Ninth Circuit's due process analysis also warrants summary reversal. To the extent that the court below assumed that Medicare beneficiaries have a constitutionally protected property interest in obtaining particular medical treatment, its decision directly conflicts with *Sullivan*. Slip op. at 17-20. In any event, the court's application of the balancing test mandated by *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976), is fatally flawed. The court essentially ignored the third factor of that test: "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirements would entail." *Id.* As a result, the Ninth Circuit's decision substantially undermines the strong government interest in maintaining a financially and medically sound Medicare program through the use of private sector managed care organizations.[3]

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[3] The Secretary's petition suggests that the implementation of the Medicare+Choice program renders the decision below moot, and that therefore the Court should vacate and remand on that ground so that the lower courts can consider the constitutionality of the new program. Pet. at 20-25. The Ninth Circuit, however, was fully aware that the Secretary had implemented new regulations, yet brushed that fact aside when it affirmed the injunction. Pet. App. 20a. Moreover, the risk-sharing contract program established under 42 U.S.C. § 1395mm (1994) is structurally similar to the new Medicare+Choice program, and the private HMO contract option is included in both programs. To the extent that the Secretary's new regulations do not comport precisely with the requirements of the injunction (e.g., by allowing more than five days for an HMO to respond to non-urgent requests for treatment), they remain subject to constitutional challenge by the respondents. Thus, the Medicare+Choice program presents essentially the same questions of government action and due process that were considered in this case. *See Northeastern Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 662 (1993) (new ordinance did not make appeal moot because it disadvantaged plaintiffs "in the same fundamental way" albeit "to a lesser degree"); *City of Mesquite v. Aladdin's Castle*,

I. THE NINTH CIRCUIT'S "FEDERAL ACTION" HOLDING CONFLICTS WITH *SULLIVAN* AND *BLUM V. YARETSKY*

The Ninth Circuit's constitutionalization of Medicare HMO administrative procedures was premised on its determination that every decision by a private HMO to deny, terminate or reduce a medical service requested by a Medicare enrollee constitutes "federal action." Pet. App. 9a-12a.[4] The court based that determination on the facts that "[t]he Secretary extensively regulates the provision of Medicare services by HMOs," pays HMOs for enrolled Medicare beneficiaries and establishes the "legal framework . . . within which HMOs make adverse determinations, issue notices, and guarantee appeal rights." Pet. App. 10a. While acknowledging that none of these factors alone would be sufficient to establish federal action, the court held that "[t]ogether they show federal action." *Id.*

This conclusion is directly contrary to *Sullivan*. Slip op. at 10. The Court there made clear that extensive government regulation of private conduct does not make the conduct

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Inc., 455 U.S. 283, 289 (1982)("[A] defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice."). Vacating and remanding on grounds of mootness would not address the lower courts' fundamentally erroneous legal rulings on those issues, which could be repeated on remand. Accordingly, the Associations submit that this case is ripe for reversal on the merits, whether summarily in light of the Court's decisions in *Sullivan*, *Blum* and *Mathews*, or after full plenary review.

[4] The injunction upheld by the Ninth Circuit requires written notice to be provided not only for denial or termination of medical treatment, but also whenever an HMO orders a "reduction" in services. Pet. App. 60a. This means that decisions, for example, to reduce the dosage or frequency of medications, or to taper off the frequency of visits by a home health care nurse to change postoperative dressings, would be deemed "government action" subject to the due process requirements imposed by the district court. *See* Second Declaration of Bruce M. Fried (then-Director of HCFA's Office of Managed Care) in Support of Defendant's Motion for Stay ("2d Fried Decl.") ¶ 6. (The 2d Fried Decl. is referred to at Pet. App. 66a-67a.)

"state action"; rather, the conduct must be coerced or significantly encouraged by the government. *Id.*; *Blum*, 457 U.S. at 1004. None of the factors relied upon by the court of appeals, taken separately or together, establishes that the government either compels or encourages the decisions made by HMOs in determining whether to deny, terminate or reduce treatments requested by their Medicare enrollees. Rather, such decisions are made entirely "by private parties according to professional standards that are not established by the [government]." *Blum*, 457 U.S. at 1008. These decisions are no more government action than were the decisions of the private insurers in *Sullivan* to suspend payment for medical treatment.

In finding "federal action," the Ninth Circuit failed to recognize the crucial distinction between the Medicare fee-for-service program and the private managed care program involved in this case. In the former, private contractors act expressly as agents of the government to make decisions whether particular medical treatments are covered and therefore reimbursable. In the private alternative managed care program, the Secretary pays HMOs a flat fee for each Medicare enrollee. The HMOs and the doctors with whom they contract are then free to determine whether a particular covered service is medically necessary for an enrollee. Enrollees are free to leave and return to the traditional fee-for-service Medicare program.[5] The fact that the Secretary

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[5] It is clear that Congress intended Medicare HMO contractors to act as private entities serving Medicare beneficiaries, not as agents of the government. In establishing the Medicare managed care option in 1972, Congress intended to make Medicare relate to HMOs "in a way that conforms more nearly to their usual way of doing business," providing, "in the case of medicare beneficiaries, the same kind of financial incentives that health maintenance organizations have with respect to their other enrollees." H.R. Rep. No. 92-231 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5076. *See also* 50 Fed. Reg. 1314 (1985) (1972 amendments were made to "conform more closely to the usual way in which HMOs operate" and thereby give them their usual incentive "to provide a continuum of services, to keep costs low, and to control utilization of services").

regulates the manner in which such services are provided by HMOs and requires an administrative appeals system for Medicare enrollees denied services does not convert this private activity into government action. *Sullivan*, slip op. at 12.

In *Sullivan*, the Court compared the private insurers' decisions to withhold payment for treatment to the decisions "to transfer Medicaid patients to a lower level of care" that the Court held in *Blum* to be private not state action. Slip op. at 11. The HMO decisions challenged in this case are virtually identical to those at issue in *Blum*. The Ninth Circuit distinguished *Blum* based on its finding that HMO decisions denying requests for medical treatment are not "merely medical judgments" but are "more accurately described as coverage decisions." Pet. App. 11a. That conclusion is simply wrong. HMO's make coverage decisions based upon medical information, not regulatory interpretation. Here, as the district court indicated, the private actions complained of were "primarily denials for Skilled Nursing Facility (SNF) care." Pet. App. 48a. Applicable regulations make clear that coverage for care in a SNF is provided only when it is "required" or "medically necessary." Pet. App. 48a. Thus, the determination whether such a service is "covered" is a contractual decision, based upon medical standards that are neither established nor authorized by the government. *Blum* is dispositive of this case.

The court of appeals relied on *Burton v. Wilmington Parking Authority*, 365 U.S. 715 (1961), to support its conclusion that government action exists because there is a "symbiotic relationship with a high degree of interdependence" between the Secretary and Medicare HMO contractors. Pet. App. 9a; *see also id.* at 11a-12a. In this respect, the Ninth Circuit committed the same error for which this Court has just reversed the Third Circuit in *Sullivan*: the court below "seems to have figuratively thrown up its hands and fallen back on language" in *Burton*. *Sullivan*, slip op. at 15. As in *Sullivan*, the lower court's reliance in this case on the broad language of *Burton* ignores this Court's subsequent

limitation of that decision to its facts. *See Sullivan*, slip op. at 16; *Blum*, 457 U.S. at 1011; *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 357-58 (1974). Medicare HMO contractors "are at least as extensively regulated as the private nursing facilities in *Blum* and the private utility in *Jackson*. Like those cases, though, the [federal] statutory and regulatory scheme leaves the challenged decisions to the judgment of [HMOs]." *Sullivan*, slip op. at 16.

II. THE NINTH CIRCUIT'S "DUE PROCESS" HOLDING CONFLICTS WITH *SULLIVAN* AND *MATHEWS V. ELDRIDGE*

In concluding that due process justified the procedures imposed by the district court's injunction, the court of appeals implicitly assumed that Medicare beneficiaries who voluntarily enroll in HMOs have a constitutionally protected property interest in receiving medical treatment. *See Sullivan*, slip op. at 18 ("Only after finding the deprivation of a protected interest do we look to see if the State's procedures comport with due process."). *Sullivan*, however, invalidates that assumption. Just as the employees in *Sullivan* had no property right to demand payment for medical treatment until they established that the treatment was both reasonable and necessary, *id.* at 19, Medicare HMO enrollees have no property right to demand the provision or continuation of medical treatment that has not been determined to be a covered benefit under their HMO contracts.

Even if its underlying assumption of a protectable property interest were correct, however, the Ninth Circuit erred in its failure properly to apply the balancing test required by *Mathews v. Eldridge*, 424 U.S. at 335. The court paid mere lip service to the "government interest" factor, asserting conclusorily that the Secretary had "failed to show that the added procedural protections sought by [respondents] would result in significant additional costs to the government." Pet. App. 17a. The court ignored completely the additional costs to the HMOs, and the effect those additional costs would have on Medicare beneficiaries, the Medicare program and the federal budget. Indeed, it ignored

the essential goal of the Medicare managed care program: to reduce Medicare costs and add benefits by taking advantage of "the health benefit design, delivery and cost containment innovations that have occurred in the private sector" and that have "helped the private market contain costs and expand health care delivery options." *See* H.R. CONF. REP. NO. 105-217, at 585, *reprinted in* 1997 U.S.C.C.A.N 176, 206.

As regulatory and administrative mandates are increased, they impair the ability of HMOs to obtain the efficiencies and offer the benefits that Congress envisioned. Indeed, under the method used to calculate the capitation payments to HMOs for Medicare enrollees, any increase in administrative costs will directly reduce the amount available to cover lower premiums for enrollees or to provide benefits, such as prescription drugs, that are not covered by fee-for-service Medicare. *See* 42 U.S.C.A. § 1395w-23(c) (Supp. 1998) ; S. Rep. No. 97-494, at 35, 1982 U.S.C.C.A.N. 781, 811. In the worst case, regulatory and administrative costs become so high that HMOs are driven out of the Medicare program entirely.

These concerns are more than theoretical. In the Fall of 1998, forty-five HMO plans that were eligible to transition to the Medicare+Choice program on January 1, 1999, decided to withdraw from the program, and fifty-four plans decided to cut back their services. *Forty-Five HMOs Leave Program, 54 Reduce Service for 1999, HCFA Reports*, 6 BNA HEALTH CARE POL'Y REP. 1955, 1955-56 (1998). In all, about 400,000 (or approximately 6.5% of the more than 6 million) Medicare risk-sharing enrollees were affected. *Id.* This mass exodus was primarily the result of the program's revised payment methodology combined with significant costs and burdens resulting from new program regulatory requirements.

By constitutionalizing the internal grievance and appeal procedures applicable to private Medicare HMO plans, the courts below have further increased those regulatory costs in a

manner not contemplated by Congress or the Secretary.[6] Those increased costs will ultimately redound to the detriment of the very beneficiaries that the lower courts were purporting to protect. As the then-Director of HCFA's Office of Managed Care (which is responsible for administering the Medicare managed care program) explained to the district court, various provisions of the injunction

> could have adverse results for beneficiaries by distracting physicians and other health professionals from the provision of care, and by increasing administrative costs to the point where medical benefits beyond those required by the Medicare program (e.g. prescription drug coverage, annual physical exams, eye and ear care, etc.) are cut. Other potential results are higher premiums and

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[6] For example, the injunction provides that when there is a denial of "acute care services" (which the injunction does not define), the medical services in dispute must continue until a final reconsideration decision is made. Pet. App. 63a. As pointed out by the then-Director of HCFA's Office of Managed Care, this provision would create a tremendous incentive for enrollees to request reconsideration regardless of the merits, since the services would be covered until the reconsideration process was completed. Aside from the additional administrative costs that HMOs would incur as a result of such meritless appeals, HMOs would be forced to pay for the provision of medically unnecessary care. This is evidenced by the fact that since 1995, more than two-thirds of HMO service denial decisions have been upheld on reconsideration. 2d Fried Decl. ¶ 10.

Another problematic aspect of the injunction is the requirement that written notice be given within five days of *any* request, *oral* or written, for treatment services (Pet.App. 60a). It will often be difficult to differentiate between "official" oral requests for services and mere "give and take" discussions between a patient and a provider about treatment options or advice. If an HMO is bound to provide written denials in connection with any encounter in which the efficacy of a specific type of treatment is discussed, a great deal of additional paperwork will be required. This would significantly burden HMOs by diverting administrative and provider resources with no corresponding benefit to patients. 2d Fried Decl. ¶ 8.

> beneficiary copayments, and even withdrawal of HMOs from the Medicare managed care program.

2d Fried Decl., ¶ 13.

In disregarding these concerns, and in summarily rejecting the Secretary's determination of the appropriate balance between cost-effective health care delivery and patient rights, the courts below violated this Court's admonition in *Mathews* that "[i]n assessing what process is due in [a particular] case, substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the procedures they have provided assure fair consideration of the entitlement claims of individuals." 424 U.S. at 349. This principle applies with particular force to the Medicare managed care program, which requires difficult compromises among competing goals and interests—a function that the judicial branch is simply not designed to perform. In these circumstances, the lower courts' apparent failure to give any weight, much less substantial weight, to the good-faith judgments of those who administer the Medicare managed care program warrants summary reversal of the decision below.

CONCLUSION

The petition for a writ of certiorari should be granted, and the decision below should be summarily reversed and the injunction vacated in light of this Court's decisions in *American Manufacturers Mutual Insurance Co. v. Sullivan*, No. 97-2000 (U.S. Mar. 3, 1999), *Blum v. Yaretsky*, 457 U.S. 991 (1982) and *Mathews v. Eldridge*, 424 U.S. 319 (1976). In the alternative, the petition should be granted, and the Court should review and reverse the decision below on the merits.

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